Department of Legislative Services

Maryland General Assembly 2020 Session

FISCAL AND POLICY NOTE Enrolled - Revised

Senate Bill 915

(Senator Kramer)

Finance

Health and Government Operations

Maryland Insurance Administration - Pharmacy Services Administrative Organizations - Regulation

This bill requires a "pharmacy services administrative organization" (PSAO) to register with the Insurance Commissioner, beginning July 1, 2021, before providing services as a PSAO to independent pharmacies in the State. A PSAO that has not registered may not enter into an agreement or a contract with an independent pharmacy or a pharmacy benefits manager (PBM). The Commissioner may adopt implementing regulations.

Fiscal Summary

State Effect: Special fund revenues for the Maryland Insurance Administration (MIA) increase from registration fees beginning in FY 2022. MIA special fund expenditures increase by \$37,000 in FY 2021 for staff. Future years reflect annualization and additional staff. General fund revenues increase, beginning in FY 2022, to the extent the Commissioner imposes civil fines or penalties on PSAOs, as discussed below.

(in dollars)	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
GF Revenue	\$0	-	-	-	-
SF Revenue	\$0	-	-	-	-
SF Expenditure	\$37,000	\$134,800	\$135,300	\$139,800	\$144,500
Net Effect	(\$37,000)	(-)	(-)	(-)	(-)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: The bill does not have a material impact on local finances or operations.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: "PSAO" means an entity that provides a contracted pharmacy with contracting administrative services relating to prescription drug benefits. "PSAO" does not include a nonprofit health maintenance organization (HMO) that operates as a group model, provides services solely to a member or patient of the nonprofit HMO, and furnishes services through the internal pharmacy operations of the nonprofit HMO.

"Purchaser" means the State Employee and Retiree Health and Welfare Benefits Program, an insurer, a nonprofit health services plan, or an HMO that provides prescription drug coverage or benefits in the State. Purchaser does not include a person that provides prescription drug coverage or benefits through plans subject to the federal Employee Retirement Income Security Act of 1974 and does not provide prescription drug coverage or benefits through insurance, unless the person is a multiple employer welfare arrangement.

Application, Renewal, Recordkeeping, and Examination

An applicant for registration as a PSAO must file an application and pay a registration fee set by the Commissioner. A registration expires on the second September 30 after its effective date. A PSAO may renew its registration for an additional two-year term if the PSAO is otherwise is entitled to be registered, files a renewal application, and pays a renewal fee set by the Commissioner. Subject to the applicable hearing provisions, the Commissioner may deny a registration or refuse to renew, suspend, or revoke the registration of a PSAO on specified grounds.

A PSAO must maintain adequate books and records regarding each independent pharmacy for which the PSAO provides services, as specified. The Commissioner may examine the affairs, transactions, accounts, and records of a registered PSAO.

Pharmacy Services Administrative Contract Requirements

A pharmacy services administrative contract (PSAC) or a contract between a PSAO, on behalf of an independent pharmacy, and a PBM or group purchasing organization (and related amendments to such contracts) may not become effective unless (1) the PSAO files the contract or, if required, amendment with the Commissioner at least 60 days before the contract or amendment is to become effective and (2) the Commissioner does not disapprove the filing within 60 days after the contract or amendment is filed. Notice from the Commissioner that a filed contract or amendment may be used in the State constitutes a waiver of any unexpired part of the filing period. The Commissioner must adopt regulations to establish the circumstances under which a contract may be disapproved and specify the types of amendments required to be filed.

A PSAC must require the PSAO to provide to an independent pharmacy a copy of any contracts, amendments, payment schedules, or reimbursement rates within five working days after the execution of a contract, or an amendment to a contract, signed on behalf of the independent pharmacy by the PSAO. A PSAC may prohibit an independent pharmacy from disclosing documents provided to the pharmacy to any competitor of the PSAO.

A PSAC must (1) require all remittances for claims submitted by a PBM or purchaser on behalf of an independent pharmacy to be passed by the PSAO to the independent pharmacy within a reasonable amount of time and (2) specify the reasonable amount of time in which the PSAO is required to pass the remittances received from the PBM or purchaser to the independent pharmacy.

A PSAO that owns or is owned by, in whole or in part, an entity that manufactures, sells, or distributes prescription drugs, biologics, or medical devices may not require, as a condition of entering into a PSAC, that an independent pharmacy purchase any drugs, biologics, or medical devices from the entity and must disclose to the Commissioner any agreement with an independent pharmacy under which the independent pharmacy purchases prescription drugs, biologics, or medical devices from the entity.

Disclosure of Ownership or Control

Each PSAO must disclose to the Commissioner, an independent pharmacy, a purchaser, or a PBM the extent of any ownership or control of the PSAO by any parent company, subsidiary, or other organization that provides pharmacy services, provides prescription drug or device services, or manufactures, sells, or distributes prescription drugs, biologics, or medical devices. Each PSAO must notify these entities within five working days after any material change in its ownership or control.

Miscellaneous Provisions

A contract or amendment to a contract submitted to the Commissioner as required under the bill is considered to be confidential and proprietary information and is not subject to disclosure under the Public Information Act.

A PSAO may not (1) misrepresent pertinent facts or policy provisions that relate to an issue in a dispute or an appeal of a decision regarding a dispute; (2) refuse to pay or reimburse an independent pharmacy or a PBM for an arbitrary or capricious reason based on all available information; (3) fail to settle a dispute promptly whenever liability is reasonably clear under one part of a policy or contract, in order to influence settlements under other parts of the policy or contract; (4) fail to act in good faith; or (5) engage in any activity that is prohibited for a PBM under Subtitle 16 of the Insurance Article or a related regulation.

Violations and Penalties

If the Commissioner determines that a PSAO has violated any provision of the bill or related regulations, the Commissioner may issue an order that requires a PSAO to (1) cease and desist; (2) take specific affirmative action to correct the violation; (3) make restitution to a person that has suffered financial injury because of the violation; or (4) pay a fine determined by the Commissioner. In addition to any other enforcement action taken by the Commissioner, the Commissioner may impose a civil penalty of up to \$10,000 for each violation of the bill.

Applicability

A PSAO contract in effect on the effective date of the bill may remain in effect if the contract is (1) filed with the Commissioner by July 1, 2021, and (2) administered in accordance with specified provisions of law as enacted by the bill.

A PSAO operating in the State before July 1, 2021, may not be required to register with the Commissioner before July 1, 2021, and must comply with specified provisions of law as enacted by the bill.

Current Law: A PBM is a business that administers and manages prescription drug benefit plans for purchasers. A PBM must register with MIA prior to providing pharmacy benefits management services. The Insurance Commissioner is authorized to examine the affairs, transactions, accounts, and records of a registered PBM at the PBM's expense.

State Revenues: Special fund revenues for MIA increase from registration fees beginning in fiscal 2022, which reflects the bill's requirement that PSAOs must register with the Commissioner on or after July 1, 2021. As the number of PSAOs currently operating in Maryland is unknown, the amount of registration revenues cannot be reliably estimated at this time.

General fund revenues increase by an indeterminate amount, beginning in fiscal 2022, to the extent the Commissioner exercises the authority to impose a civil fine or civil penalty on a PSAO if the Commissioner determines that a PSAO has violated any provision of law or regulations.

State Expenditures: MIA special fund expenditures increase by \$37,015 in fiscal 2021, which accounts for the bill's October 1, 2020 effective date. This estimate reflects the cost of hiring one company licensing analyst (beginning January 1, 2021) to establish the registration process, adopt any regulations, and begin registering PSAOs by July 1, 2021. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Ongoing Operating Expenses Total FY 2021 State Expenditures	2,818 \$37,015
Onacina Onaratina Evnancas	2 010
One-time Start-up Expenses	4,890
Salary and Fringe Benefits	\$29,307
Position	1

In fiscal 2022, expenditures increase further to hire one full-time investigator (beginning July 1, 2021) to review PSAO contracts and contract amendments. Future year expenditures reflect full salaries with annual increases and employee turnover and ongoing operating expenses.

Small Business Effect: PSAOs, some of which may be small businesses, must register with the Commissioner and comply with the bill's requirements. Small business independent pharmacies may benefit.

Additional Information

Prior Introductions: None.

Designated Cross File: HB 978 (Delegate Kelly, *et al.*) - Health and Government Operations.

Information Source(s): Judiciary (Administrative Office of the Courts); Office of Administrative Hearings; Maryland Insurance Administration; Department of Legislative Services

Fiscal Note History: First Reader - February 26, 2020

rh/ljm Enrolled - April 1, 2020

Revised - Amendment(s) - April 1, 2020 Revised - Clarification - April 1, 2020

Analysis by: Jennifer B. Chasse Direct Inquiries to:

(410) 946-5510 (301) 970-5510